

REMARKS

Claims 1-26 are pending in the subject application.

Restriction Requirement

In the Office Action, the Examiner required restriction to one of the following six Groups of inventions:

- I. Claims 9-10, drawn to a method of determining whether a subject has pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying with an antibody to ebaf;
- II. Claims 11-13, drawn to a method of determining whether a subject has pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying with nucleic acid probes which hybridize to a nucleic acid encoding ebaf;
- III. Claims 19-20, drawn to a method of assessing the efficacy of therapy to treat pre-neoplastic or neoplastic lesions in transitional epithelial cells in a subject undergoing treatment for pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying diagnostic samples with an antibody to ebaf;
- IV. Claims 21-23, drawn to a method of assessing the efficacy of therapy to treat pre-neoplastic or neoplastic lesions in transitional epithelial cells in a subject undergoing treatment for pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying diagnostic samples with nucleic acid probes which hybridize to a nucleic acid sequence encoding ebaf;
- V. Claims 24-26, drawn to a method of assessing the prognosis of a subject who has a pre-neoplastic or neoplastic lesion comprising assaying a diagnostic sample of the subject for protein expression; and
- VI. Claims 24-26, drawn to a method of assessing the prognosis of a subject who has a pre-neoplastic or neoplastic lesion comprising assaying a diagnostic sample of the subject for nucleic acid expression.

The Examiner indicated that Claims 1-8 link inventions I and II, that the restriction requirement between the linked inventions is subject to the nonallowance of the linking Claims 1-8, and that upon the indication of allowability of the linking claims,

the restriction requirement to the linked inventions shall be withdrawn. The Examiner also indicated that Claims 14-18 link III and IV inventions, that the restriction requirement between the linked inventions is subject to the nonallowance of the linking Claims 14-18, and that upon the indication of allowability of the linking claims, the restriction requirement to the linked inventions shall be withdrawn.

In response to the restriction requirement, applicant hereby elects, *with traverse*, the invention identified by the Examiner as Group I, i.e., Claims 9-10, drawn to a method of determining whether a subject has pre-neoplastic or neoplastic lesion in transitional epithelial cells comprising assaying with an antibody to ebf. Claims 1-10 encompass the elected invention.

Applicant respectfully points out that the groups of inventions identified by the Examiner are all linked by the procedure of assaying a diagnostic sample for the expression of ebf, either to determine whether a subject has a pre-neoplastic or neoplastic lesion in transitional epithelial cells, or to assess the efficacy of therapy to treat the lesion, or to assess the prognosis of a subject who has the lesion. Applicant maintains that a search for one group would necessarily identify art pertinent to the other groups. Applicant also respectfully points out that if a search and examination of multiple groups can be made without serious burden on the Examiner, the Examiner must examine the application on the merits, even though it includes claims to independent or distinct inventions (MPEP §803). Applicant maintains that it would not place an undue burden on the Examiner to examine at least Groups III and V along with Group I. Accordingly, reconsideration and rejoinder of groups of inventions identified by the Examiner are respectfully requested.

Information Disclosure Statement

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant would like to direct the Examiner's attention to the eleven references that are listed on enclosed Forms PTO/SB/08A-B (2 pages). Copies of the 6 non-patent references are

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Appl. No.: 10/014,320
Filed: December 11, 2001
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attached hereto. Applicants are submitting the subject Information Disclosure Statement pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Accordingly, no fee is deemed necessary in connection with the filing of this Information Disclosure Statement.


CONCLUSION

A check for \$1,080.00 is enclosed for the fee for a small entity for filing a petition for a five month extension of time. No other fee is deemed necessary in connection with the filing of this response. However, if any other fee is required to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully submitted

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Dated: New York, New York
March 30, 2007

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